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19 June 1963

The Honorable John E. Fogarty
United States House of Representatives
Washington, D.C.

Dear Mr. Fogarty:

This note accompanies a copy of a short article that has been sent to 'SCIENCE' with a view to its possible publication in the near future, perhaps as a "Letter." It presents strong objections to some of the recently introduced restrictive regulations pertaining to the management of grants of the Public Health Service and suggests ways in which such regulations might be altered.

I hope that you will find time to read this document, the substance of which has been approved by the Dean and Chairmen of the Departments of the School of Medicine, as well as the Provost of Yale University, and that it and other protests will help to restrain present attempts to regulate research workers in ways that will diminish the rate of scientific progress in America.

If you deem it to be appropriate to send copies of this article to other members of the Congress, we would greatly appreciate your advice concerning the key individuals of the Senate and the House of Representatives that might be selected. Any help that you could give us in the very near future would be greatly appreciated, since mailings should occur almost at once if anything worth while possibly is to be accomplished.

Sincerely yours,



Arnold D. Welch, Ph.D., M.D.
Eugene Higgins Professor of Pharmacology
Chairman

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A Critique of Some Recently Introduced Regulations Pertaining to Research Grants of the Public Health Service

During recent weeks storms of criticism of newly instituted regulations relating to the management of research grants of the National Institutes of Health (NIH), a division of the Public Health Service (PHS), have arisen amongst the staffs of many universities and institutes. From these staffs, from many scientific societies, and from various individual scientists, with varying degrees of articulateness and reasonability, has come much heat, but a paucity of light with respect to suitable means of circumventing the problems forced upon the NIH by a critical Congressional Committee. This Committee, taking note of indications of occasional lack of adequate responsibility by grantees of the PHS, has made what would appear to be reasonable demands that scientists not be treated as especially privileged citizens and that greater fiscal control should be exercised in the expenditure of the hundreds of millions of dollars awarded annually by the various agencies of Congress for the support of scientific research. It is important to note that the funds of the PHS are awarded on the basis of evaluations made by carefully selected scientists, who serve as consultants to the Surgeon General, and who carefully scrutinize each application for a grant, with respect to the objectives, the proposed means of obtaining them, and the appropriate amount of money needed to support each application that is recommended for approval.

It is unfortunate that some members of the Congress seem to have been persuaded that scientific research can operate productively when subjected to rigid fiscal controls, as can a variety of industrial or other operations supported by Federal funds. Differences between basic research and contractual assignments often are not clearly evident to those lacking experience in coping with the frustrating difficulties that inevitably are encountered in the accomplishment of fundamental research, particularly in biological and medical fields. Accordingly, it is only too easy for critics to characterize scientists

working in these areas as unbusinesslike, unworldly or even irresponsible, for whom "fiscal controls" are necessary - for their own good. Yet experienced investigators, particularly those with some administrative as well as teaching responsibility (as is the lot of a large percentage of NIH-grantees), know full well that important discoveries simply cannot be made in an atmosphere of restrictive rules, regulations and bureaucracy, with suggestions that scientists should be able to predict the course of things to come, and to guide their behavior accordingly. Great ideas or scientific accomplishment cannot be engendered by administrators or committees, and the greater the amount of "fiscal control," with its inevitable red tape, the lesser will be the productivity of science in America.

The important point, therefore, is how to convince the Congress that, in attempting to attain suitable fiscal responsibility and to prevent possible abuses in the expenditure of research funds by the occasional grantee, the means found should not diminish appreciably the previously unparalleled rate of advance in scientific discoveries and accomplishments of the last fifteen years, largely a result of the wisdom and generosity of the Congress and the hitherto remarkably wise policies of such disbursing agencies as the National Institutes of Health and the National Science Foundation.

What has gone wrong? Perhaps it is to a considerable degree a result of unprecedently rapid growth, with (1) a great increase in the number of scientists being trained or supported by Federal funds, (2) a rapid increase in the number and size of the grants, and (3) almost inevitable differences in opinion as to what constitutes essential freedom to do good research, as compared to what some apparently regard as unfettered license. In any case, although attainment of the desired degree of "fiscal control" can be insured by the development of severely restrictive regulations, the inevitable price to be paid is a reduced

over-all accomplishment. Consequently, the Congress ought to have the collective courage to question the wisdom of those "directives" of its committees that have led to the establishment of restrictive regulations by unwilling but apprehensive agencies, since these restrictions are certain to affect adversely the desired rate of attainment of scientific progress.

What are some of these newly made regulations that are regarded so unfavorably by scientists?

1. The requirement that grantee-investigators not be allowed to alter their objectives in a major way, except after permission has been recommended by a committee or granted by officials within the agency from which the funds were obtained.

2. The establishment of rules requiring that records be kept concerning the actual percentage of time that grant-supported scientists devote to a research project.

3. The interpretation that full-time employment with funds derived from a research grant should prohibit even a modest and sensible participation of scientists in such regularly scheduled educational activities in an institution as are conducive to the scholarly development of the individual.

4. Restrictions upon freedom to shift funds within the several budgetary categories of a research grant, even when a grant has been morally committed for several years in advance, with those inevitable changes in orientation that develop and that require a maximal amount of flexibility in the management of research funds.

Perhaps even more important than the unduly restrictive regulations developed by the apprehensive agencies are those now being initiated by comptrollers and administrative officers within some of the equally apprehensive universities and research institutes. Already many of the latter have placed - or have attempted

to place - even more severe controls upon the scientists than have the Federal agencies. These controls reflect an apparently desirable goal, namely, the development of houses that are even cleaner than those properly desired by the Congress; unfortunately, however, these overly zealous efforts may have a most untoward effect upon the houses of science; sterility rather than cleanliness! Accordingly, let us consider as briefly as possible each of the above-listed restrictive regulations, and some constructive suggestions for their modification.

1. Modification of research goals. Vigorous reaction on the part of scientists led to a very recent alteration of a most objectionable earlier restriction that would have prevented any significant modification of an initially approved research objective by a qualified investigator. Experienced scientists, recognizing that new findings may either emphasize or diminish the importance of envisaged goals, and that such restrictions could place almost intolerable encumbrances upon progress, protested strongly. As a result, the Surgeon General of the PHS announced recently an alteration in this regulation; in essence, the regulation now limits alteration of research objectives to "changes in methodology, approach, or other aspects of the project that would expedite achievement of its (my italics) research objectives, including changes that grow logically out of the approved project and serve the best scientific strategy." This is a major step forward, but even this statement does not go far enough, for it does not permit an essential change in the orientation of a very competent investigator, particularly one judged to be of such merit as to have been given a moral commitment for long-term support (up to seven years). Especially in the latter situation, it is the proven competence of an investigator that is being backed, and his area of investigative activity; to accomplish the desired end, and to avoid the concept of a contractual relationship to attain a stated objective, all that is needed, in the above-quoted section of the new regulation, is to

change the italicized word "its" to "his." Such a *modification* would put the responsibility for quality and objectives where it should be, in the hands of the carefully selected investigator. Furthermore, it would have the very salutary strategic effect of not encouraging the submission of grant applications that are vague with respect to objectives and therefore difficult to evaluate, since it would be recognized that precision in the delineation of a proposed investigation, although of great value to advisory committees concerned with evaluation, would not restrict an investigator to an area that new research could demonstrate to be unproductive.

2. With respect to keeping records of "time and effort," nothing would seem more reasonable at first glance, in order to prevent diversion of effort, loafing or other abuses (although it is difficult to regard these as characteristic of research scientists). Perhaps none of the several new regulations has caused more irritation among scientists than has this one; not only is it unrealistic and unworkable, but it demands intellectual dishonesty. Good investigation cannot be done under the shadow of a time clock and effective scientists do not work a week of 37.5 or 40 hours (although their technical assistants usually do). A regulation that requires that either "per cent of time" (or "per cent of effort") or "hours per week" be recorded asks for the impossible, since research cannot be done consistently according to any prescribed pattern of required time or effort. Contributions to research cannot be estimated on the basis of the number of hours at either the bench or the desk, for equally important intellectual contributions actually may occur during conferences with scientific colleagues and students, and even more with time for reflection: in the library, while shaving, or in the quiet of one's bed! Let us realize, therefore, that neither "per cent of time" nor "per cent of effort" can be gauged as with clerks, and scientists should not be required to make outwardly plausible but actually untenable estimates of it.

3. There appear to be some curious differences between the kinds of dollars awarded by the PHS in support of research and training and how they may be used; these may be defensible in terms of bookkeeping and "fiscal control," but not in terms of attainment of intellectually desirable goals. Thus, as an example, a PHS research grant that fully supports a scientist permits him to give only an occasional unscheduled lecture, but a modest amount of scheduled teaching, desired by the individual for his own intellectual stimulation and growth, the respect of his peers, and the development of his career, is forbidden. On the other hand, the same man might be employed legally, and on a full-time basis, on a PHS-supported research training program and be so overburdened with teaching that time for productive research would be minimal or absent.

Clearly, neither extreme is desirable, and although it may be rare that the second situation is encountered today, the former one is not uncommon, and a much more liberal interpretation is needed of what is reasonable in the way of modest and sensible participation in teaching that is desired by the theoretically full-time research worker, and actually is beneficial, not detrimental, to his research. To accomplish this end does not require the introduction of time clocks, but only a common sense definition of reasonability - and what could be simpler than an average participation of up to perhaps 6 hours a week, rather than, let us say, up to 15 per cent of his time or effort?

4. Some restrictions upon freedom to shift funds within the various budgetary categories of a previously approved grant would seem to be entirely warranted if scientists are not to be regarded as the best judges of sensible and productive ways to obtain desired objectives within the framework of the total amount of money provided for the conduct of their own research. But if the scientists are not to be trusted, who is? As the new rules now stand, it can be predicted that a rapidly expanding army of bureaucratic officials will be drafted

to rule upon the multitudinous and laboriously documented appeals for budgetary readjustments that are certain to be presented continually by grantee scientists throughout America. Who can evaluate and rule upon these appeals? Presumably former scientists who, for one or more of many possible reasons, find greater satisfaction in "regulating" science than in contributing to it creatively. In other words, the power of decision has been taken from those most qualified to evaluate the wisdom of budgetary alterations and has been transferred to Washington, where it is to be in the hands of men who are unfamiliar with the research - and who must learn to some degree to be negativistic, if their efficiency in turn is not soon to be questioned. Will not the amount of money relegated to the salaries of this new bureaucracy, as well as for the time of scientists who ought to be working or thinking, be far more wastefully expended than that presumably to be spent unwisely each year by a small percentage of less severely controlled grantees? If the fear is that some institutions will use research funds to rehabilitate physical facilities (or in some other wasteful manner), presumably with a view to the better accomplishment of the research, will this not be controlled adequately by the well-known activities of the General Accounting Office, which scrutinizes the records of expenditures by institutions and has the power (and exercises it) to force restitution? If undue travel by scientists for conferences and the exchange of ideas is a legitimate and really fearful problem (which can be doubted), a restriction on alterations of this aspect of research budgets perhaps is defensible. It would seem, however, that in all other categories the best way to foster scientific progress is to delegate authority to the principal investigator (and his administrative associates in an institution) to expend the allocated research funds with maximal freedom. The investigator, as an applicant, has already been judged by juries of his peers to be highly qualified for the conduct of

research, a reasonable sum of money has already been granted with which to gain the desired objectives, and maximal attainment will occur only with minimal bureaucratic interference in the guise of attaining fiscal responsibility.

In conclusion, then, it is suggested that the objectives of the Congress to further scientific research and the training of new scientists, as well as the best means of attaining these ends for the public good, need to receive further consideration - carefully and promptly. For this purpose, it has been suggested by others that the National Academy of Sciences, established a century ago to advise the government concerning problems in which both scientific acumen and mature judgment are needed, be invited to arbitrate in the present controversy. What could be more appropriate in this case?

It is not too late for additional changes to be made in unworkable or too restrictive regulations and for the National Institutes of Health to be allowed to foster scientific investigation and training, as they have done so well in the past, not only by the careful allocation of grants, but also by minimal interference with sensible management of research funds by principal investigators. Specifically, there is need (1) to liberalize further the present limitations upon modifications of research objectives, (2) to abolish the keeping of records by research workers of "time and effort," (3) to liberalize the interpretation of "full-time" and to permit scientists entirely paid from research grants to participate to a modest degree in teaching, and (4) to remove restrictions upon the transfer of funds between the different categories of a budget set up to permit an initially desirable research objective to be attained.

It is unthinkable that the errors of a very small proportion of the grantees of the Public Health Service and of other Federal agencies should be so exaggerated that in purging them, serious and lasting harm be done to the progress of science. The people of the world probably have received more permanent

benefit from unimpeded scientific research and development than from almost any other application of American intelligence, ingenuity, enterprise and public money.

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*The substance of this letter by the chairman of the Department of Pharmacology, Yale University School of Medicine (former chairman of the Study Section on Pharmacology and Experimental Therapeutics and now chairman of the Study Section on Chemotherapy, PHS), has received the approval, as well as the constructive criticism of the other chairmen of the departments and the Dean of the School of Medicine, and the Provost of Yale University.